

REMARKS/ARGUMENTS

Reconsideration of this application is respectfully requested. To this end, *petition is hereby made for a (3) three-month extension of time to respond to the outstanding Office Action of June 15, 2010.* The fee for this extension is being submitted with this paper.

Nevertheless, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140.

Claims 31, 32 and 58 – 64 are pending in this application, claims 33 – 57 and 65 – 93 having been withdrawn from further consideration. Upon entry of this Amendment, claims 31, 32, 60, 63 and 64 will be amended to clarify the invention and/or to better conform them to U.S. patent practice, claims 58, 59, and 61 will be amended to better conform them to U.S. patent practice, and claim 62 will be cancelled. In addition, new claims 94 – 101 will be added.

In making the foregoing claim amendments, Applicant notes that a feature from claim 62 (poly-paraxylylene polymer) has been incorporated into amended claim 31, features from claims 31, 58, 61, and 62 (biocompatible metal coating) have been incorporated into new claim 94, and that new claims 95-101 correspond to various features previously presented in claims 31, 58-61, 63 and 64.

In the outstanding Office Action, the Examiner rejected claims 31, 32 and 58-64 under 35 U.S.C. §112, second paragraph, as being indefinite because of either the inclusion of incorrect punctuation or a lack of clarity in certain terms used in the claims. In response to the claim rejections under § 112, second paragraph, claim 31 has been written in a single sentence, claim 32 has been amended to clarify that the layer or coating of claim 32 is the same layer or coating

as in claim 31, claim 60 has been amended to clarify that it is the base material that comprises a polyurethane layer surrounding a silicone layer, claim 63: has been amended to clarify that the silicone is hard silicone, and claim 64 has been amended to clarify that reference is made to the layer or coating of the property improving means. In view of these amendments, it is believed that the claim rejections under § 112, second paragraph, should now be withdrawn.

In the outstanding Office Action, the Examiner also rejected, as being unpatentable under 35 U.S.C. §103(a), claims 31, 32, 58-61 and 63 over Fierro (U.S. Patent Publication No. 2002/0183588) in view of Stoy *et al.* (U.S. Patent No. 4,480,642), and claim 62 over Fierro and Stoy, as applied to claims 31, 58 and 61, and further in view of Wijeratne *et al* (U.S. Patent No. 6,287,315). The Examiner's rejections are respectfully traversed.

For a claimed invention to be obvious over a combination of references, there must have been some reason as to why one of ordinary skill in the relevant art would have combined the references to produce the claimed invention. Here, the claims of the present application are not obvious over the combination of Fierro, Stoy and Wijeratne because, even assuming, *arguendo*, that the Examiner properly combined these references, the result would still not be the claimed invention.

In rejecting previously pending claim 62 (now part of claim 31) under 35 USC § 103, the Examiner relied on a combination of three different references. However, the Examiner has acknowledged that the combination of Fierro and Stoy does not set forth the use of the claimed material for the layer or coating property improving means. To compensate for this deficiency, the Examiner states the following:

The property improving means of the combination is directed to friction reducing material. Wijeratne teaches low-friction material including polyurethane, silicone

or PTFE (polytetrafluoroethylene) may all be substituted for one another. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to use polytetrafluoroethylene in place of the material for reducing friction as set forth in the combination as a substitution of functionally equivalent materials as shown by Wijeratne. Such a substitution would produce predictable results with a high expectation of success.

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However, Wijeratne does not disclose the use of poly-paraxylylene polymer (Parylene) or a biocompatible metal coating as a property improving means. Since these materials are not disclosed in the cited prior art, the independent claims must be considered to define non-obvious devices. For this reason alone, the claims of the present application are not obvious over the combination of Fierro, Stoy and Wijeratne.

With regard to the primary Fierro reference cited by the Examiner, independent claim 31 of the present application defines an implantable constriction device for constricting penile blood vessels of a patient for treating impotence. Independent claim 31 defines the claimed implantable constriction device as comprising a base material comprising a layer of polyurethane and a layer of silicone. Applicant contends that this combination of materials gives unexpectedly good properties regarding fatigue resistance, *etc.*

The Examiner alleges that Fierro teaches an implantable constriction device as shown in Figure 3 of Fierro. Applicant contends that this is wrong, in that Fierro teaches a sling 1 with a pad 6, the sling being used for stabilizing the urethra by means of urethral suspension. *See* Fierro, para. [0008] and [0009]. Applicant notes that, as can be seen from Figure 13 of Fierro, the neck of the bladder or the urethra 13 lays on the pad 6, which thereby permits a reduction, or even an elimination of, the friction between the sling and the neck of the bladder or the urethra. Thus, there is no restriction or constriction of the urethra, as opposed to the claimed device,

which is a constriction device. Applicant contends that it must be appreciated that the technical problems associated with a constriction device and a sling are widely different.

Thus, for the foregoing reasons, Applicant contends that the claimed invention, as defined by independent claim 31, is not obvious over Fierro in combination with the other cited references. And because independent claim 31 is not obvious over Fierro in combination with the other cited references, dependent claims 32, 58-61, 63 and 64 are also not obvious over Fierro in combination with the other cited references. Applicant further contends that, for the foregoing reasons, new claims 94 – 101 are also not obvious over Fierro in combination with the other cited references.

The Examiner also provisionally rejected claims 31, 32, 58 – 64 on the ground of non-statutory, “obviousness-type” double patenting over claims 1 – 4, 8 – 12, 17 – 21, 23 – 27, 32 – 44, 53 – 60, 72 – 76 and 78 – 81 of co-pending Application No. 11/889,756.

In response, Applicant requests reconsideration of the provisional double patenting rejection in view of the fact that the claims of the present application have been amended to overcome the cited art. Alternatively, Applicant respectfully requests that the provisional double patenting rejection be placed in abeyance until allowable subject matter is indicated as being present in this application. At that time, consideration will be given as to whether double patenting exists between the claims of this application and those of co-pending Application No. 11/889,756, and if so, how to respond to it. In this same regard, Applicant notes that the present application was filed on August 19, 2005, almost two years before the August 16, 2007 filing date of Application No. 11/889,756 cited in the double patenting rejection, and that the Manual of Patent Examining Procedure provides that:

If a "provisional" statutory double patenting rejection is the only rejection remaining in both applications, the examiner should withdraw that rejection in the application with the earlier filing date and permit that application to issue as a patent. If both applications were filed on the same day, the applicant should be given an opportunity to elect which of the two should be allowed. In either situation, the examiner should maintain the double patenting rejection in the other application as a "provisional" double patenting rejection, which will be converted into a double patenting rejection when one application issues as a patent.

MPEP 804 I.B.2 (Emphasis added).

Finally, the Examiner's attention is drawn to (i) the fact that an Information Disclosure Statement is being filed in this application, and (ii) because of the subject matter disclosed and claimed therein, to co-pending Application Nos. 10/623,801 and 10/522,540 of Applicant and the art cited by the Examiners in such applications' office actions.

In view of the forgoing, it is believed that this application is otherwise now in condition for allowance, which action is earnestly solicited. If any issues remain with regard to this application, the Examiner is urged to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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